PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : B67D — A2

(11) International Publication Number: WO 00/01612

(43) International Publication Date: 13 January 2000 (13.01.00)

(21) International Application Number: PCT/US99/07476

(22) International Filing Date: 5 April 1999 (05.04.99)

(30) Priority Data:
09/110,617 6 July 1998 (06.07.98) US

(71) Applicant: IEP GROUP, INC. [US/US]; 6320 Angus Drive, Raleigh, NC 27613 (US).

(72) Inventors: JEWETT, Warren, R.; 125 Palace Green, Cary, NC 27511 (US). GENOVA, Perry, A.; P.O. Box 16036, Chapel Hill, NC 27516 (US).

(74) Agents: SANTUCCI, Ronald, R. et al.; Kane, Dalsimer, Sullivan, Kurucz, Levy, Eisele and Richard, LLP, 20th floor, 711 Third Avenue, New York, NY 10017 (US).

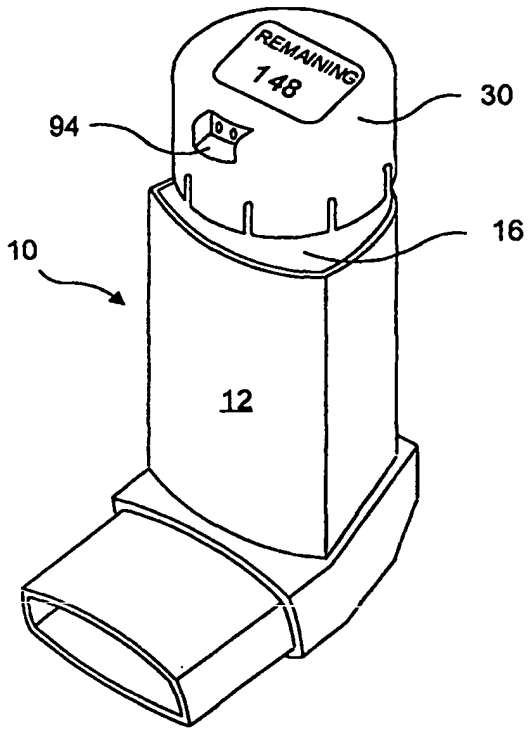
(81) Designated States: AU, CA, JP, NO, NZ, ZA, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
Without international search report and to be republished upon receipt of that report.

(54) Title: COUNTER FOR FLUID DISPENSER

(57) Abstract

The disclosure is of a device for indicating a plurality of data relating to the condition of fluid dispensations remaining in a container for holding and dispensing metered quantities of the fluid. The device sequentially displays the time elapsed since the most recent dispensation, the number of fluid dispensations remaining in the container and the number of dispensations made during the previous twenty–four hours. In one embodiment, a foam spring is included to closely match the pressure required to signal that a dispensation has occurred with the pressure required to make the dispensation, thereby minimizing false counts and ensuring that each dispensation is included in the count. The foam spring also provides a hermetic seal to the microelectronic means. The microelectronic means is mounted on a glass sheet and is hermetically sealed thereto.



Express Mail Label No.
EV332062968US

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

Counter for Fluid Dispenser

Background of the Invention

Field of the Invention

This invention relates to fluid dispensers, and, more particularly, to a counter for a fluid dispenser for indicating the time elapsed from the most previous dispensation, the number of dispensations remaining in a canister from which the dispensations are made and the number of dispensations made in a predetermined time period.

Brief Description of Related Art

A wide variety of fluid dispensers are known and commercially available to dispense a metered proportion of a contained fluid from a container. For example, U.S. Patent No. 3,749,290 describes a trigger actuated dispensing pump assembled with a fluid container. Upon actuation, a measured proportion of the contained fluid is dispensed from the container.

Of particular importance as fluid dispensers are metered dose inhalers employed to administer pharmacologically active compounds to humans and animals. The use of such metered dose inhalers is well known, and the art has developed over the past twenty-five years to cover many versions of the basic concept of a "pumping" type medication applicator. The device may be manually pumped (such as described in U.S. Patent No. 5,284,132) or a pumping like cycle may be utilized. The medication may also be repeatedly released from a pressurized disposable canister to create repeated sprays or inhalations as needed.

Representative of the early inhalers for oral and intra-nasal administration of medications are those described in, for example, U.S. Patent Nos. 3,361,306, 3,183,907, 3,565,070, 4,206,758,

4,803,978, 4,934,358, 4,955,371, 5,060,643 and 5,351,683. Representative of nasal-pharyngeal inhalers for large mammals, such as a horse, is that described in U.S. Patent No. 5,062,423.

Metered dose inhalers (MDIs) are, at present, the most efficient and best-accepted means for accurately delivering medications in small doses to an animal's respiratory tract. Therapeutic agents commonly delivered by the inhalation route include bronchodilators (B2 agonists and anticholinergics), corticosteroids, and anti-allergics. Inhalation may also be a viable route for anti-infective, vaccinating, systemically acting and diagnostic agents, as well as anti-leukotrienes, anti-proteases and the like.

MDIs are available in several types. Most frequently, MDIs comprise a pressure resistant container (canister) typically filled under a super-atmospheric pressure with a product such as a drug dissolved in a liquified propellant, or micronized particles suspended in a liquified propellant. The container is fitted with a metering valve. The valve is movable from an inner (charging) position to an outer (discharging) position. A spring bias holds the valve in the charged position until forced into the discharge position. Actuation of the metering valve allows a metered portion of the canister content to be released, whereby the pressure of the liquified propellant carries the dissolved or micronized drug particles out of the container and to the patient. A valve actuator also functions to direct the aerosol as a spray into the patient's oropharynx. Surfactants are usually dissolved in the aerosol formulation and can serve the dual functions of

lubricating the valve and reducing aggregation of micronized particles.

Representative of pharmaceutical formulations for use in metered dose inhalers (MDI) are those described in U.S. Patent No. 5,190,029. The MDI devices for administering such pharmaceutical formulations are also well known as seen for example in the descriptions given in U.S. Patent Nos. 3,361,306, 3,565,070 and 4,955,371, which are incorporated herein by reference thereto.

A disadvantage arising from use of the known devices is that the patient cannot determine the amount of medicament in the aerosol container at any given time. The containers are generally not transparent to view, being light protective of the contents. Shaking them will not always reveal auditory information as to their contents. In an extreme case this could mean that the patient, possibly suffering from severe bronchospasm or like emergency condition and needing a dose of medicament, will find that the aerosol container will not dispense a dose, because its contents have been previously exhausted. The problem has been recognized and consideration given to solutions. For example, U.S. Patent No. 4,817,822 describes an inhaler device that includes a counting means for indicating the relative emptiness of a container or the number of doses dispensed. However, this inhaler counting mechanism is physically attached to the aerosol container as well as the inhaler, such as by a retaining ring or retaining cap. In one embodiment, the counting means is a separate sleeve fitting on the up-turned bottom of the aerosol container. It is easy to lose, not being integrated with the inhaler, but an ancillary unit

slipped over the loose aerosol container. In another embodiment, the counting means requires a secured attachment to the aerosol container neck, which prevents removal of the container from the inhaler, even when empty. The inhaler device is only useful for use with the original aerosol canister and can not be used with aerosol refill canisters.

U.S. Patent No. 5,020,527 presents an improvement over the dose counting means of U.S. Patent No. 4,817,822 wherein the mechanical counter can be replaced with an electronic counter. The improved inhaler can indicate the number of doses remaining in the aerosol container. However, the device is not fool-proof in operation, which can be a disadvantage in the hands of a severely debilitated, confused or forgetful patient. In households that include small children, they have been known to "play" with the MDIs when unsupervised access is possible. Infants can accidentally reset or interfere with established counts in the mechanical devices. For example, the counter can be accidentally reset, obviating its usefulness and, in fact, misleading the patient as to the true number of doses remaining in the container. In addition, the counter can not be automatically reset when a full, new aerosol container (refill) is to be used. This can affect the accuracy of the count carried out.

In addition, the inhaler of U.S. Patent No. 5,020,527 still employs a mechanical trigger to actuate the counting means. It is subject to triggering of the counter without actual administration of a dose from the container, for example, when the aerosol container is removed and

the inhaler device washed and disinfected, independent of the aerosol container.

U.S. Patent No. 5,622,163 describes a counter for fluid dispensers, which is mounted on the end of a fluid container. Dispensation of a metered dose simultaneously activates a light emitting diode (LED) to visually signal the user as to the number of dispensations remaining in the container. The LED is programmed to flash twice per second for ten seconds after each dispensation after 180 of 200 dispensations. An audible tone is programmed to sound after 190 of 200 dispensations. After the 200th dispensation, the LED is programmed to remain illuminated until the battery is exhausted or the canister is replaced. Alternatively, a continuous audible tone may be sounded after the 200th dispensation. While the counter described in U.S. Patent No. 5,622,163 provides a signal to the user that the canister is nearing the end of its useful life, the counter does not indicate the actual number of dispensations remaining in the container.

Thus, there is a need for a counter for fluid dispensers capable of indicating the time elapsed since the most recent dispensation, the number of dispensations remaining in the canister and the number of dispensations made in a predetermined time period. Date and time of usage can be stored in an application specific integrated circuit (ASIC) memory for the life of the MDI to be available to the healthcare provider in order to determine patient compliance and pattern of use. This data is important for several aspects of disease management.

The counter of U.S. Patent 5,622,163 describes a device wherein the top end of the counter

includes a flexible sheet, which, when depressed, activates a micro-switch to indicate that a dispensation has been made. The micro-switch is set to operate at a range of 3 to 7 lbs. of pressure as compared with a typical pressure requirement of 3 lbs. to dispense the fluid in the container. False counts are minimized by closely matching the pressure required to trip the micro-switch and the pressure required to dispense a dose from the fluid container. Given the range of pressure required to trip the micro-switch and the typical pressure required to make a dispensation, it is possible that a dispensation can be made without tripping the micro-switch, thereby leading to an inaccurate count. The micro-switch is subject to wear, especially wear due to fatigue during its useful lifetime. Although the micro-switch may be initially calibrated to a particular trigger pressure, the actual pressure required to trip the micro-switch may increase or decrease after repeated uses. Accordingly, the accuracy of the count, particularly when the canister is nearing exhaustion, may be compromised. When the canister is nearing exhaustion, it is most critical that the count is accurate to prevent the situation described above, where a person needing a dose of the medicament is in an emergency situation. Relying on the pressure required to trip the micro-switch to prevent such false counts limits the versatility and may increase the cost of the counter. Further, by relying on the flexible sheet and housing to hermetically seal the counter will subject the counter to harmful exposure to moisture and other contaminants should a breach of the

integrity of the flexible sheet and/or housing occur.

Accordingly, there is a need for a counter for a fluid dispenser wherein the pressure required to signal a dispensation can be closely matched to the pressure required to make the dispensation, thereby virtually eliminating falsely counted dispensations. There is a further need for a counter for a fluid dispenser that provides increased protection against moisture and other harmful contaminants, including the fluid compound contained within the fluid container.

These and other problems associated with the inhalers and other fluid dispensers of the prior art are solved by the present invention, described hereinafter. The device of the invention is economical to manufacture and assemble with fluid containers and is disposable when the container is empty, in the same manner currently followed in disposing of the containers.

The device of the invention is intended for use with one fluid container and is disposable with it when the contents are emptied. One need not reset a counter with the errors attendant with such a procedure.

Summary of the Invention

The above and other beneficial objects are obtained in accordance with the present invention by providing a counter for fluid dispensers, which incorporates a foam polymer trigger spring to closely match the pressure required to signal a dispensation from a fluid container with the pressure required to make the dispensation. The counter further may include a microchip, in a "flip chip" type package, which is mounted on a surface

of a glass sheet and encapsulated in an epoxy resin to hermetically enclose and seal the microchip, protecting the microchip from moisture and other harmful contaminants.

The device of the invention is useful to maintain a running inventory of a predetermined quantity of fluid to be dispensed from a container and to signal when a predetermined number of dispensations remains in the container. It is relatively simple to operate, even by young children (6 to 12 years of age). For example, the invention enables one to maintain a count of medication dispensations remaining for use in metered dose inhalers and other fluid dispensers.

The above and other beneficial objects are obtained in accordance with the present invention by also providing a counter for fluid dispensers, which displays automatically in sequence, the time elapsed since the most previous dispensation, the number of dispensations remaining in the container and the number of dispensations made in the previous twenty-four hours and stores time and date of usage in volatile memory.

The device of the invention is useful to maintain a running inventory of a predetermined quantity of fluid to be dispensed from a container and to signal the actual number of dispensations remaining in the container. The device of the invention further provides the time elapsed since the most recent previous dispensation and the number of dispensations made over a predetermined time period to aid in record-keeping, to ensure patient compliance and to assist forgetful persons, children and their parents and elderly persons in maintaining their treatment program. A stored

record of patient usage is available to the healthcare provider for download to a computer through a conventional RS 232 connection integral with the counter. It is relatively simple to operate, even by young children (6 to 12 years of age). For example, the invention enables one to maintain an accurate count of medication dispensations remaining for use in metered dose inhalers and other fluid dispensers and to obtain additional data pertaining to recent dispensations.

Brief Description of the Drawings

Embodiments of the present invention will be described with reference to the accompanying drawings in which:

Figure 1 is a perspective view of an embodiment metered dose inhaler of the invention shown in assembly with a metered dose inhaler aerosol canister.

Figure 2 is a view as in Figure 1, but with added means for downloading recorded use data to a health provider's computer, such as a personal computer.

Figures 3-5, inclusive, are fragmented views of the inhaler 10, showing the device 30 of the invention displaying in sequence the use data collected, calculated and stored in memory. Figure 3 displays the number of doses remaining in canister 16. Figure 4 displays the number of uses in the last 24 hour period and Figure 5 displays the number of hours since the previous dose was administered. This information is critical to the management of many disease entities such as asthma.

Figure 6 is an exploded view of the counter device shown in Figures 1 and 2.

Figure 7 is a cross-sectional side view of the assembly 10 illustrated in Figure 1 and depicts further structural details of the embodiment.

Figure 8 is a cross-sectional side view of the device 30 seen in Figures 1-6, but after activation to effect a dose administration.

Figure 9 is a bottom plan view of the embodiment microelectronic indicator means of the counter device shown in Figures 1-3.

Figure 10 is a top plan view of the microelectronic indicator means shown in Figure 6.

Figure 11 is a bottom plan view of an embodiment circuit mounting of the microelectronic means shown in Figures 9-10.

Figure 12 is a side elevational view of the circuit mounting shown in Figure 11.

Figure 13 is an illustration of an embodiment microelectronic circuit component of the microelectronic indicator means shown in Figures 9-10.

Figure 14 is a side sectional view of a pump associated with the neck of a fluid container, as taken from Figure 9 of U.S. Patent No. 3,749,290, incorporated herein by reference thereto, and modified to include assembly with the device of the invention shown in Figures 1-13.

DETAILED DECRIPTION OF THE PREFERRED EMBODIMENTS OF THE INVENTION

Those skilled in the art will gain an understanding of the invention from a reading of the following description of the preferred embodiments when read in conjunction with a viewing of the accompanying drawings of Figures 1-14, inclusive, where identical numerals in each figure represent identical elements.

Figure 1 is a perspective view of an embodiment assembly 10 of the invention, which comprises an open-ended, hollow tube 12 assembled with an aerosol canister 16 upon which there is mounted a counter device 30 of the invention. The assembly 10 is a metered dose inhaler (MDI), as is known and conventional in the prior art, but improved by the inclusion of the device 30, which contains a microelectronic means for signaling dispensations from the canister 16, calculating the number of dispensations remaining in the canister 16, indicating the calculated number of remaining dispensations and other functions.

Figure 2 is a view as in Figure 1, but where the embodiment of Figure 1 is assembled with socket connection means 31 for downloading patient use data collected, to a personal computer or other data handling apparatus.

Figures 3-5, inclusive, are fragmented views of the assembly 10 shown in Figure 1, limited to the counter device 30 and a plurality of sequentially displayed messages controlled by the microelectronic means. As depicted in Figure 3, the first display is a number corresponding to the number of doses remaining in canister 16. In Figure 4, the second sequenced display is a number corresponding to the number of doses administered in the last 24 hours. In Figure 5, the displayed number corresponds to the number of hours since the previous dose was administered.

Now referring to Figure 6, there is shown an exploded view of counter device 30, which includes housing 32, microelectronic indicator means 40 and foam spring 42.

The device 30 housing 32 is preferably made of a transparent or translucent polymeric resin material, and shaped like an inverted cup. The preferred synthetic polymeric resin material for fabricating the counter device 30 is light transmitting so that when exposed to an interior relatively low-level light source, it appears luminous and illuminates adjacent areas. The resin body of the device 30 may be coated on interior surfaces thereof (not shown in Figure 6) to selectively reflect inwardly or diffuse light, as desired.

Representative of the synthetic polymeric resins useful to mold housing 32 of counter device 30 are thermoplastic polyolefins, polyurethanes, polycarbonates and poly(methacrylate), particularly those which are semi-rigid and have some flexibility to facilitate installation and operation as described hereinafter. Housing 32 includes a transparent lens 34 formed in the top surface thereof. Lens 34 may be integrally formed with housing 32 or may be a distinct member mounted within a complimentary opening of housing 32. Lens 34 may be of any size and configuration to create a viewing port to view display 46 and to magnify display 46, if necessary.

The interior of housing 32 is configured to receive microelectronic indicator means 40, foam spring 42 and bushing 44 which is adhesively attached to canister 16. Microelectronic indicator means 40 is shown in Figure 6 as a generally rectangular member, but it will be understood that microelectronic indicator means 40 may be of any suitable configuration. A complimentary anterior chamber 48 is defined within housing 32 to receive

microelectronic indicator means 40. Rotation of microelectronic indicator means 40 with respect to housing 32 is prevented by the rectangular shape of microelectronic indicator means 40, and, therefor, proper orientation of microelectronic indicator means 40 with respect to lens 34 is ensured. Although microelectronic indicator means 40 may be of any configuration, the particular configuration chosen should prevent the relative rotation of microelectronic indicator means 40 with respect to housing 32 and lens 34.

A posterior chamber 50 (see Figure 7) is defined within housing 32 for receiving foam spring 42 and bushing 44. When foam spring 42 and bushing 44 are installed in housing 32, foam spring 42 is received by a complementary pocket 52 formed in the top surface of bushing 44, and the top surface of foam spring 42 abuts the under surface of micro-electronic indicator means 40. Housing 32, as stated above, is preferably formed of a polymeric resin. Polymeric resin materials have an inherent resiliency, which provides resiliency to tabs 36. When assembling bushing 44 with housing 32, a ramped portion of detents 38 (see Figure 7) sliding against the side walls of bushing 44 urge tabs 36 radially outwardly, increasing the effective diameter of the opening of housing 32. Once bushing 44 is fully seated within housing 32, tabs 36 are urged radially inwardly so that the flat upper faces of detents 38 maintain contact with the bottom surface of the side walls of bushing 44, retaining bushing 44 in housing 32.

As shown in Figure 7, a cross-sectional side view of an embodiment inhaler assembly 10 of the invention. The inhaler assembly is essentially a

hollow tube 12 having a first open end 14, which by size and configuration is adapted to receive in assembly an aerosol canister 16. A small vent aperture 13 may be advantageous to vent the tube 12 hollow 20 during use, allowing ambient air into the interior of metered dose inhaler 10. The aerosol canister 16 is fitted with a conventional metering valve, (not shown) and spray stem 18. Such canisters are commercially available from Bespak Co., North Carolina, U.S.A and may contain any of the pharmaceutical preparations conventionally used in oral and nasal medicators, such as described, for example, in U.S. Patent No. 5,190,029. The assembled tube 12 and canister 16 locates the canister 16 partially within hollow 20 of tube 12. Open end 22 communicates with hollow 20 and is adapted by size and configuration to form a mouthpiece for insertion in the oral cavity of a patient and to couple or sealingly engage with the oral lips for inspiration and expiration of the breath of a mammal. Alternatively, open end 22 can be adapted to engage with the patient's nasal passages. Within hollow 20 is fixedly mounted a spray-directing element 23, which includes a continuous internal conduit 24. The conduit 24 couples with the stem 18 of the aerosol canister 16 and directs a metered dose therefrom out of nozzle 26 as a spray toward the open end 22 of tube 12 when the canister 16 is pushed downwardly by the user. The valve of canister 16 is activated to release a metered dose when the user pushes the canister 16 downward, forcing stem 18 against the element 23. In a preferred embodiment of the invention, the interior walls of the tube 12 at open end 14 and radially inward therefrom may be

closely fitted to the exterior walls of canister 16 (a sliding engagement), so that canister 16 will move freely within hollow 20 until stem 18 is stopped by element 23, but is sufficiently closely fitting to avoid escape of aerosol spray through open end 14 during use. As illustrated both in Figure 1 and Figure 2, the up-turned canister 16 slidingly engaged in the hollow 20 through open end 14 is accessible to be pushed down on element 23. When depressed upon element 23, the valve on the canister 16 opens to release a metered dose of the aerosol formulation, through stem 18 and conduit 24 to spray from nozzle 26 toward the open end 22 of tube 12. One dose is released from aerosol canister 16 each time it is fully depressed upon element 23. Release of pressure on aerosol canister 16 returns aerosol canister 16 to the non-depressed position, charging the valve for a further discharge of a dose when the valve is again activated. As illustrated in Figure 7, the valve is concealed within the neck of canister 16 and functions when the stem 18 is pushed interiorly into canister 16. The valve itself is not shown in Figures 1, 2 or 6, 7, being conventional and within the enclosure of canister 16 itself.

Integral to canister 16, adhesively attached and non-removable from the exterior of canister 16 in a location on the up-turned bottom of canister 16 is bushing 44 component of a hermetically sealed counter device 30 for the containment of microelectronic means for determining the number of doses remaining in the canister 16 after each activation and release of a metered dose. The positioning of counter device 30 on the up-turned bottom of canister 16 enables the user to depress

the canister 16 as described above by pressing on the top of counter device 30 housing 32 with a finger. The containment of the micro-electronic counter means 40 within a hermetically sealed counter device 30 housing 32 permits the user to remove the canister 16 at any time, with adhesively attached counter device 30, to wash the tube 12 (inside and out) with water, soaps, disinfectants and antiseptic solutions with no damage to or interference with an ongoing count, as will be described more fully hereinafter. A preferred adhesive is a cyanoacrylate adhesive. This is important, because sprays of many aerosol formulations leave tacky residues, which will entrap dust and dirt particles. Some provide a media for the growth of undesired microorganisms. If the growth of these microorganisms is unchecked, they can serve as a source of infection for the patient, and will often introduce pathogens into the patent's respiratory tract.

As also illustrated in Figure 7, foam spring 42 has a generally ring shape. Foam spring 42 is made of a foamed elastomer, having either an open or closed-cell structure. Preferably, foam spring 42 is made of foamed butylene rubber having a closed cell structure, although other materials, such as a polyurethane elastomer or a polyvinyl-chloride elastomer, may be used. Foam spring 42 is fabricated to have a certain compression strength and resiliency so that a predetermined trigger pressure (3 to 7 lbs.) is required to compress foam spring 42 and actuate the microelectronic indicator means 40 as will be described hereinafter. When assembled with housing 32, foam spring 42 is slightly compressed within posterior chamber 50 to

seal fluidly tight anterior chamber 48, thereby hermetically sealing microelectronic indicator means 40 within housing 32. As illustrated in Figure 7, bushing 44 has a pocket 54 adapted to receive the upturned bottom of canister 16 and is adhesively secured thereto by a cyanoacrylate adhesive.

Foam spring 42 under finger pressure ensures switch contact 62 is depressed to contact switch pad 68 (see Figures 7-8) to record a dispensation as will be described below.

Figure 8 is a view of the counter device 30 as shown in Figure 7, but after counter device 30 has been pressed downward to effect a count by closure of switch 62 with switch pad 68.

Figure 9 is a bottom view of the embodiment microelectronic indicator means 40. Micro-electronic indicator means 40 includes a circuit board 60 (see Figures 7-8), on which a display 46 is mounted. Display 46 is preferably a liquid crystal display (LCD) capable of displaying at least three digits. It will be understood that the number of digits displayable by display 46 should be equal to the order of magnitude of the number of dispensations contained in container 16. LCD devices are well known and may be, for example, of the type described in U.S. Patent Nos. 4,804,953, 5,227,899 and 5,227,901. Micro-electronic indicator means 40 include memory and timer sections for recording the time that a dispensation was made, and such recorded data may be downloaded or transferred to a computer or other instrumentation through terminals 94 (see Figure 1 and Figure 2) through the agency of connector adapter cap 31 for analysis and ensuring patient

compliance with a treatment program. Micro-electronic indicator means 40 may further include an audible alarm, which may provide an audible sound when, for example, the last dispensation from canister 16 is made. Alternatively, the audible alarm may sound when the number of dispensations remaining in canister 16 has fallen below a predetermined number or a predetermined percentage of the number of dispensations in a full canister 16, such as ten percent.

As illustrated in Figures 7-9, a power source battery 58 is secured to circuit board 60 by retainer 78. Retainer 78 is made of an electrically conductive material, preferably a metal, such as aluminum or steel, formed by stamping. Retainer 78 has a plurality of clips 56 for securing retainer 78 and battery 58 to circuit board 60 (see Figure 10). Battery 58 may, for example, be a long-life battery such as the conventional and known nickel-cadmium or lithium batteries providing circa 1.0 to 3.0 volts of electrical power. Retainer 78 is in electrical communication with the anode of battery 78 and includes switch contact 64 for electrical contact with switch pad 66 of circuit board 60 (see Figure 7) for providing electrical power to circuit board 60. Retainer 78 includes switch contact 62 for electrically contacting switch pad 68 of circuit board 60 when a dispensation is made from canister 16. As illustrated in Figure 7, switch contact 62 is normally positioned out of electrical contact with switch pad 68. When a dispensation from canister 16 is made, switch contact 62 is brought into electrical contact with switch pad 68, and, when canister 16 is restored to its charging

position, switch contact 62 returns to its non-contacting state, as shown in Figure 7, due to the resiliency of foam spring 42.

Figure 10 is a top plan view of the micro-electronic indicator means 40 illustrated in Figure 9.

Now referring to Figure 12, the circuitry of circuit board 60 is shown in detail. As described above, circuit board 60 includes pad 66 in continuous electrical contact with the anode of battery 58 and switch pad 68 for electrical communication with switch contact 62 when a dispensation from container 16 is being made. Circuit board 60 further includes a battery pad 70 in continuous electrical contact with the cathode of battery 58. Electrically conductive tracings 74 are provided on the back surface of circuit board 60. An Application Specific Integrated Circuit (ASIC) 76 is mounted on the back surface of circuit board 60 and the terminals thereof are in electrical communication with respective tracings 74. ASIC 76 is preferably manufactured in a "flip-chip" package, which is known and conventional, the terminals of which are bonded to respective tracings 74 by a cured conductive cement or epoxy. The conductive cement or epoxy may be of a type curable by ultraviolet light.

As illustrated in Figure 12, circuit board 60 is a multi-layer glass board having a diffuser 80 on a viewing side thereof and a reflector 82 opposite the diffuser. Tracings 74 (see Figure 11) are on the layout surface 84. As battery 58 is mounted on the reflector side of circuit board 60, an electrically conductive epoxy resin 72 is applied to subtend the two layers and provide

electrical communication between battery pad 70 and layout surface 84. A layer of clear UV-curable liquid epoxy or other sealant, not shown, may be applied to the layout surface 84 to cover tracings 74 and ASIC 76 and cured to hermetically seal tracings 74 and ASIC 76, protecting tracings 74 and ASIC 76 from moisture and other contaminants.

Circuit board 60 is preferably made of two sheets of glass, each of which have a thickness of approximately 1.1 mm, with tracings 74 being formed of a conductive ink applied to the layout surface 84. Reflector 82 is light reflective and provides reflected light for proper imaging of the digits of LCD display 46.

Mounted on circuit board 60 and powered by battery 58 is an Application Specific Integrated Circuit (ASIC) 76 such as a logic array or microprocessor programmed to process electrical signals from the switch 62 and trigger the LCD display 46 to give a numerical readout of the number of dispensations remaining in container 16. The ASIC 76 may trigger display 46 to continuously or briefly display the number of remaining dispensations. ASIC 76 is a control means and can be a digital integrated circuit serving the control functions enumerated herein, including the memory, timing and communications functions described above. If ASIC 76 includes the memory and timing functions described above, ASIC 76 may be programmed to cause display 46 to display such additional parameters, such as the date and time of the most recent dispensation, the time elapsed since the most recent dispensation and the number of dispensations made during a predetermined time period, such as the most previous twenty four

hours. ASIC 76 may further be programmed to cause display 46 to display the additional parameters sequentially after each dispensation or repeatedly cycling through the parameters.

Figure 13 is a schematic plan showing embodiment circuitry means for the microelectronic indicator means 40 described above. ASIC 76 may be programmed at the manufacture thereof, to sense and count down the predetermined number of doses remaining in canister 16 after each use of the assembled apparatus. For example, when a full canister 16 is inserted into the inhaler assembly 10, with counter device 30 attached and secured to canister 16, and the upturned bottom of canister 16 is depressed to cause an initial delivery of a metered dose of medication from canister 16, ASIC 76 will start the count process. During normal usage, canister 16 may be removed at any time with device 30 for washing the inhaler assembly 10 and then replaced without altering the on-going count.

ASIC 76 may be programmed at the manufacture thereof for a total count of, for example, 200 doses. Each time the patient depresses the medication canister 16 for an inhaled dose of, for example Albuterol®, foam spring 42 is compressed by downward digit pressure on the top surface of housing 32, and housing 32 slides inwardly toward the bottom of upturned canister 16. Supplying sufficient pressure to overcome the resistance of foam spring 42, urges switch contact 62 against switch pad 68. Closure of switch contact 62 triggers the microelectronic indicator means 40 to subtract "one" from the ongoing count. After each dose, display 46 displays the number of doses remaining in canister 16. This visual signal

indicates the actual number of doses remaining in the canister 16 and provides an indication of the canister 16 approaching an exhausted state.

By the construction of counter device 30 and the particular configuration of foam spring 42 to provide a predetermined resistance to triggering a count, one can ensure that false counts will not occur, for example, while carrying the assembly 10. Foam spring 42 can be configured, by the selection of material, inner and outer diameters and thickness, to require a pressure of, for example, 4 to 5 lbs. to close switch contact 62, (see Figures 7-8) where the typical pressure to dispense a dose from an MDI is approximately 3 lbs. By closely matching the pressure required to close switch contact 62 and to dispense a dose from container 16, false counts are minimized while ensuring that each dispensation is properly reflected in the count.

Figure 14 is a cross-sectional side elevational view of a trigger actuated dispenser pump 10a mounted on a container 16a (shown fragmented). The container 16a may be non-transparent so that one can not visually determine the contents thereof. Adhesively secured to the trigger 17a for actuating pump 10a is a device 30a, identical in all respects to the device 30 described above. When the trigger 17a is pulled by the operator's finger, a digit is placed on the top of housing 32a which actuates through the switch contact 62 the ASIC 76 previously described. As mentioned above, the device 30a can be constructed with a foam spring 42, which will function at a predetermined pressure, generally within the range of about 3 to 10 lbs., closely matched to the

pressure required to make a dispensation, to avoid false counts during operation of the trigger 17a and to ensure that each dispensation is included in the count.

Thus, the several aforementioned objects and advantages are most effectively attained. Although a single preferred embodiment of the invention has been disclosed and described in detail herein, it should be understood that this invention is in no sense limited thereby, and its scope is to be determined by that of the appended claims.

WHAT IS CLAIMED IS:

1. A counter for indicating a plurality of data relating to the condition of dispensations remaining in a fluid container, said container for holding and dispensing a metered quantity of a fluid, said counter comprising:

a tubular housing having a first end, a second end and a tubular body joining the first end and the second end, said tubular body together with the first end and the second end defining a hollow chamber;

a first closure closing the first end;

a second closure closing the second end;

microelectronic means mounted in the chamber for receiving a signal upon each dispensation of the fluid from the fluid container and calculating said plurality of data;

means for indicating the plurality of data after each dispensation;

means for signaling to the microelectronic means upon the occurrence of each dispensation, positioned proximal to the first end of the tubular housing; and

means on the tubular housing for mounting the counter on the fluid container in a position where dispensation simultaneously activates the signaling means.

2. The counter according to claim 1, wherein said plurality of data comprises the number of dispensations remaining in the container, the time elapsed since a most recent dispensation and a number of dispensations made in a predetermined time period.

3. The counter according to claim 1, wherein said indicating means sequentially indicates the plurality of data.

4. The counter according to claim 2, wherein said predetermined time period is the previous twenty-four hours.

5. The counter according to claim 1, wherein said indicating means comprises a liquid crystal display disposed within the hollow chamber.

6. The counter according to claim 5, wherein said liquid crystal display is a numeric display displaying a plurality of digits.

7. The counter according to claim 1, wherein the tubular housing is fabricated from a synthetic polymeric resin, which is at least in part light transmitting therethrough.

8. The counter according to claim 1, wherein the housing is hermetically sealed.

9. The counter according to claim 1, further comprising a switch for sending the signal to the microelectronic means, said switch being disposed within the hollow chamber.

10. The counter according to claim 1, wherein the microelectronic means comprises an application specific integrated circuit programmed to indicate the plurality of data after each dispensation.

11. An assembly for administration to the respiratory tract of an mammal orally or intranasally, a pharmacologically active medication, said assembly comprising:

a hollow closed tube having a first open end and a second open end, said first end adapted by size and configuration to receive an aerosol canister containing a predetermined number of unit doses of the medication in the hollow tube, said second open end adapted by size and configuration to couple with the oral or nasal cavities of a mammal;

an aerosol canister having a top, a bottom and a metering valve on the canister top for the release of a predetermined number of unit doses of medication from the aerosol canister, the improvement, which comprises:

microelectronic means, mounted on the canister bottom and having an Application Specific Integrated Circuit programmed to receive a signal generated by the valved release of a single unit dose from the aerosol canister and to calculate, upon receiving the signal, the time elapsed since the most recent dose, the number of predetermined unit doses minus the number of doses released and the number of doses made in a predetermined time period; and

a means to signal the calculation.

12. The assembly according to claim 11, wherein said predetermined time period is the previous twenty-four hours.

13. The assembly according to claim 11, wherein the hollow tube is fabricated from a synthetic polymeric resin.

14. The assembly according to claim 11, wherein the means for signaling comprises a liquid crystal display.

15. The assembly according to claim 14, wherein said liquid crystal display is a numeric display displaying a plurality of digits.

16. An event counter for indicating the number of dispensations remaining in a container for holding and dispensing metered quantities of a fluid, said event counter comprising:

a tubular housing, having a first end, a second end and a tubular body joining the first end and the second end, said tubular body together with the first end and the second end defining a hollow chamber;

a first closure, closing the first end;

a second closure, closing the second end;

microelectronic means mounted in the chamber and positioned proximal to the first end of the tubular body, for receiving a signal upon dispensations of the fluid from the container, calculating the number of dispensations remaining in the container and indicating the calculation upon each dispensation;

means positioned proximal to the first end of the tubular housing for signaling to the microelectronic means upon the occurrence of each dispensation;

means on the second end of the tubular housing for slidably mounting the event counter on the fluid container in a position where dispensation of a metered dose simultaneously activates the means for signaling; and

means for biasing said first closure axially apart from said second closure.

17. The event counter according to claim 16, wherein the tubular housing is fabricated from a synthetic polymeric material, which is at least in part light transmitting therethrough.

18. The event counter according to claim 16, wherein said microelectronic means is hermetically sealed in said housing.

19. The event counter according to claim 16, wherein the biasing means is a compression spring made of a foamed elastomer.

20. The event counter according to claim 19, wherein said foamed elastomer is butylene rubber.

21. The event counter according to claim 16, wherein said foam spring has a closed cell structure.

22. The event counter according to claim 16, further comprising a switch disposed within the hollow chamber for sending the signal to the microelectronic means.

23. The event counter according to claim 16, wherein the means for signaling comprises a liquid crystal display.

24. The event counter according to claim 23, wherein the liquid crystal display is a numeric display.

25. The event counter according to claim 16, wherein the microelectronic means comprises an application specific integrated circuit programmed to indicate the number of fluid doses remaining in the container after each dispensation.

26. The event counter according to claim 25, wherein the application specific integrated circuit is a flip chip package mounted onto a surface of a glass sheet.

27. The event counter according to claim 26, wherein the application specific integrated circuit is hermetically sealed onto the surface of the glass sheet.

28. The event counter according to claim 27, wherein the application specific integrated circuit is hermetically sealed onto the surface of the glass sheet by encapsulating the application specific integrated circuit in a layer of an epoxy resin.

29. The event counter according to claim 27, further comprising:

means for storing the date and time of a most recent dispensation; and

means for communicating the date and time stored by the storing means to a data processing means.

30. The event counter according to claim 29, wherein said data processing means comprises a computer and said communication means comprises a means for downloading the stored data and time to the computer.

31. The event counter according to claim 30 wherein the microelectronic means comprises an application specific integrated circuit programmed to sequentially indicate after each dispensation the number of fluid doses remaining in the container, a time period elapsed since a most recent dispensation and the number of dispensation made during a predetermined time period.

32. The event counter according to claim 31, where the application specific integrated circuit is a flip chip package mounted onto a surface of a glass sheet.

33. The event counter according to claim 32, wherein the application specific integrated circuit is hermetically sealed onto the surface of the glass sheet.

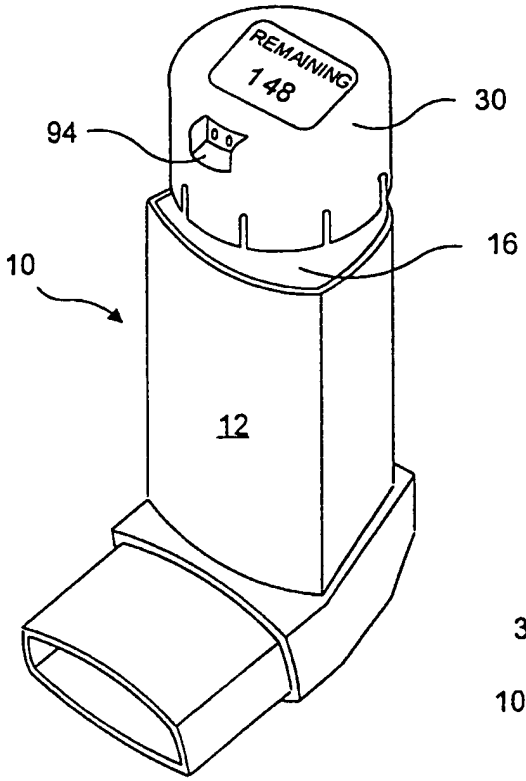


FIG. 1

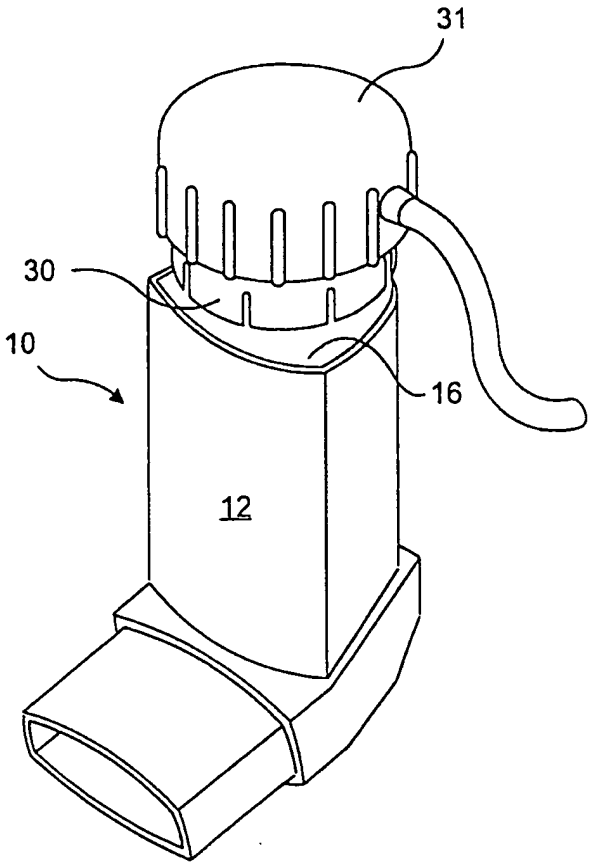


FIG. 2

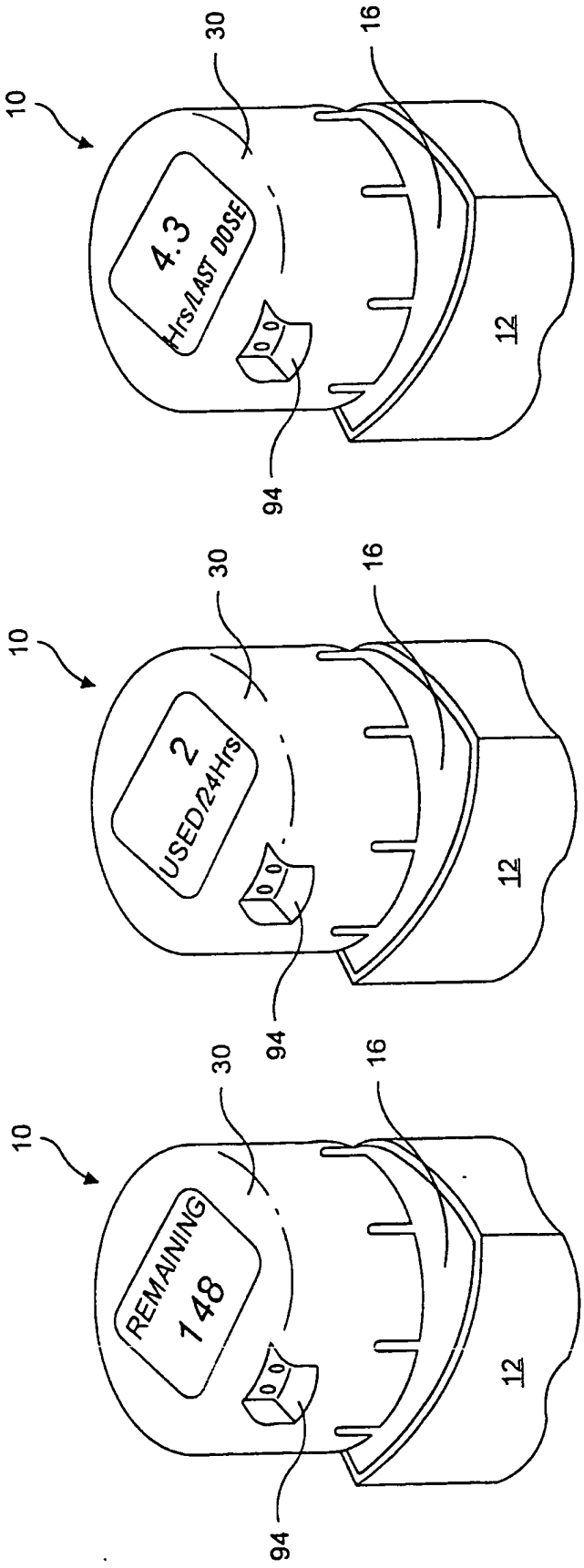


FIG. 5

FIG. 4

FIG. 3

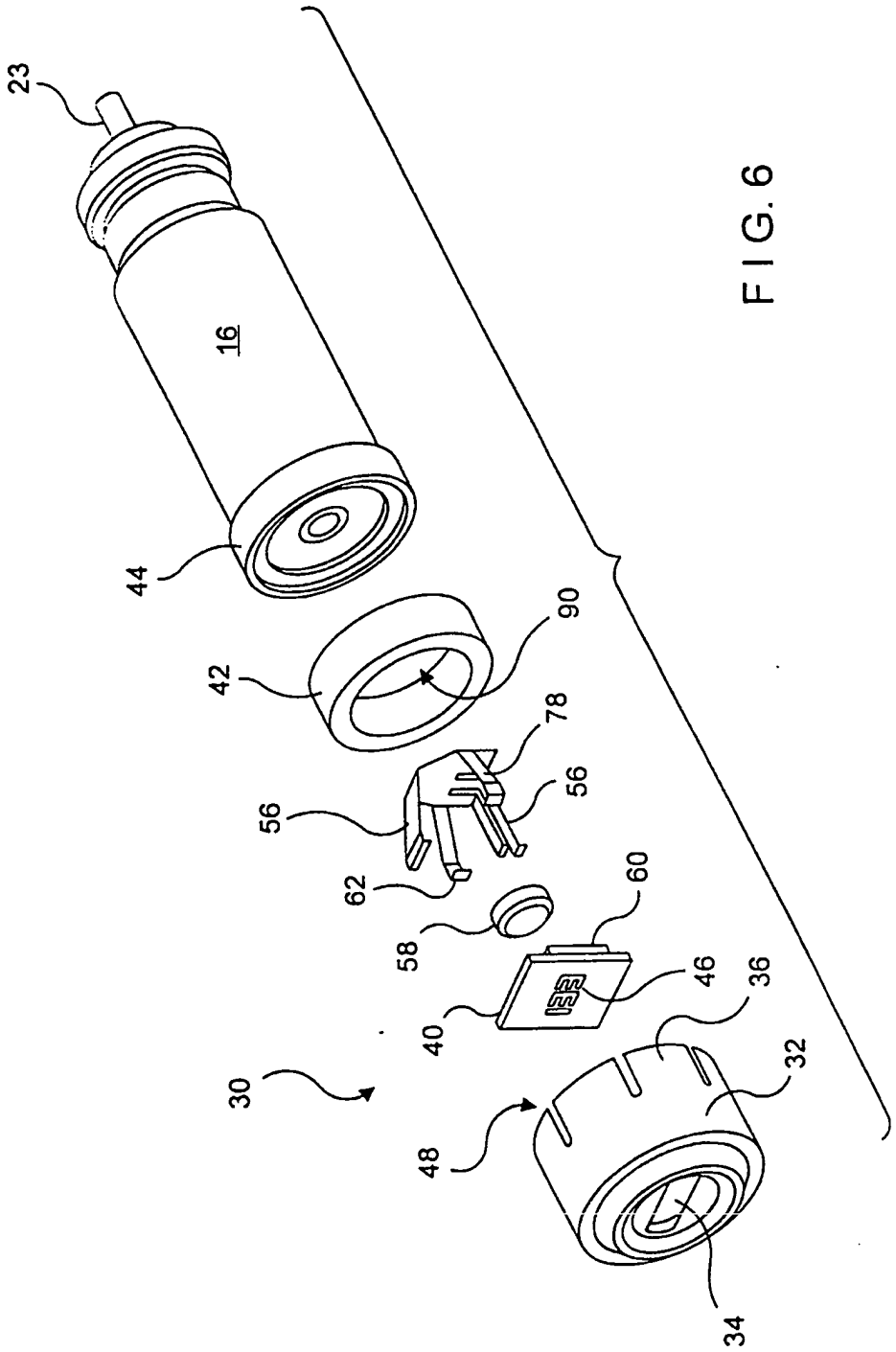


FIG. 6

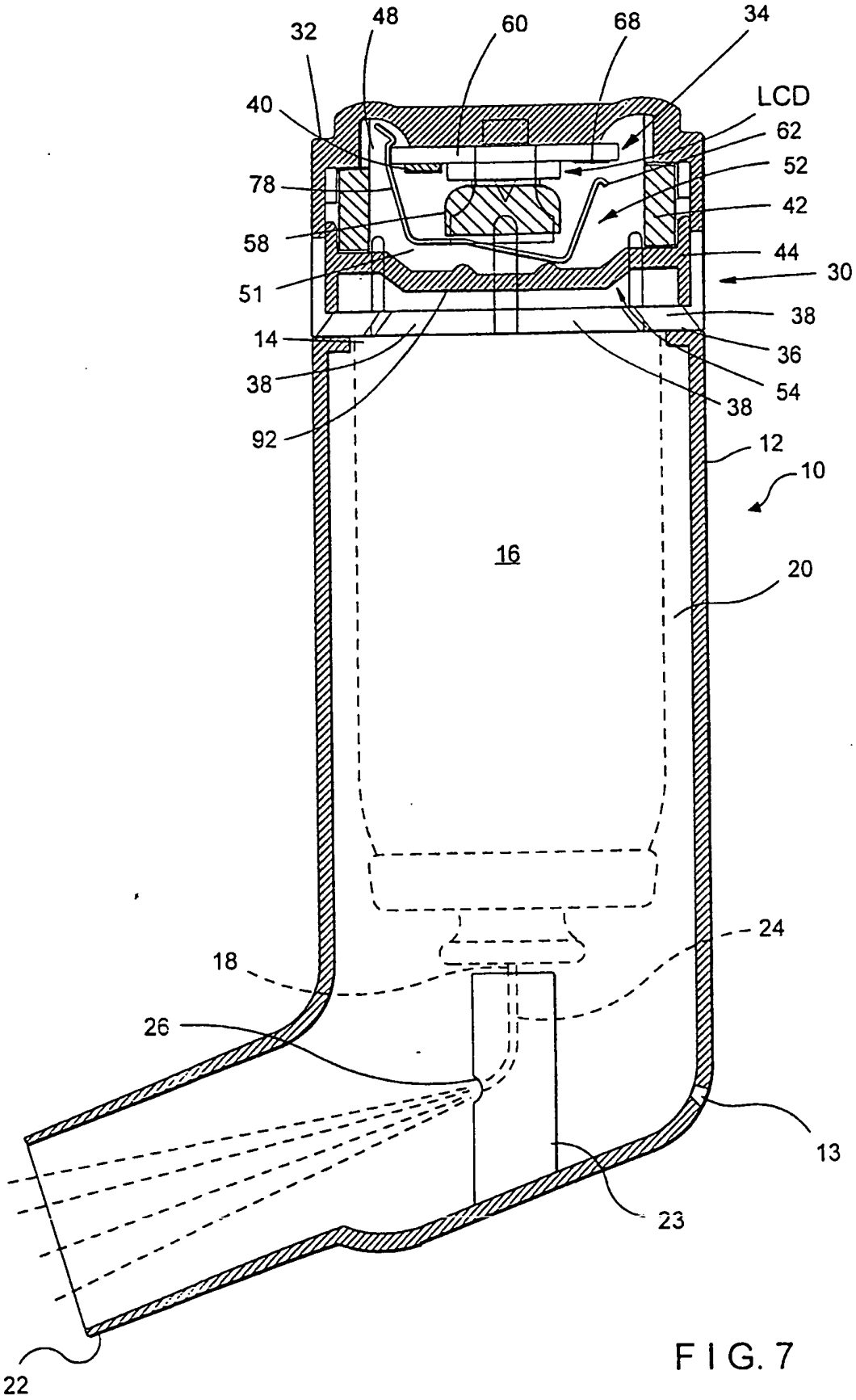

32
48
60
68
34
40
LCD
62
52
78
42
58
44
30
51
38
14
36
38
54
38
92
12
10
16
20
24
18
26
13
23
22

FIG. 7

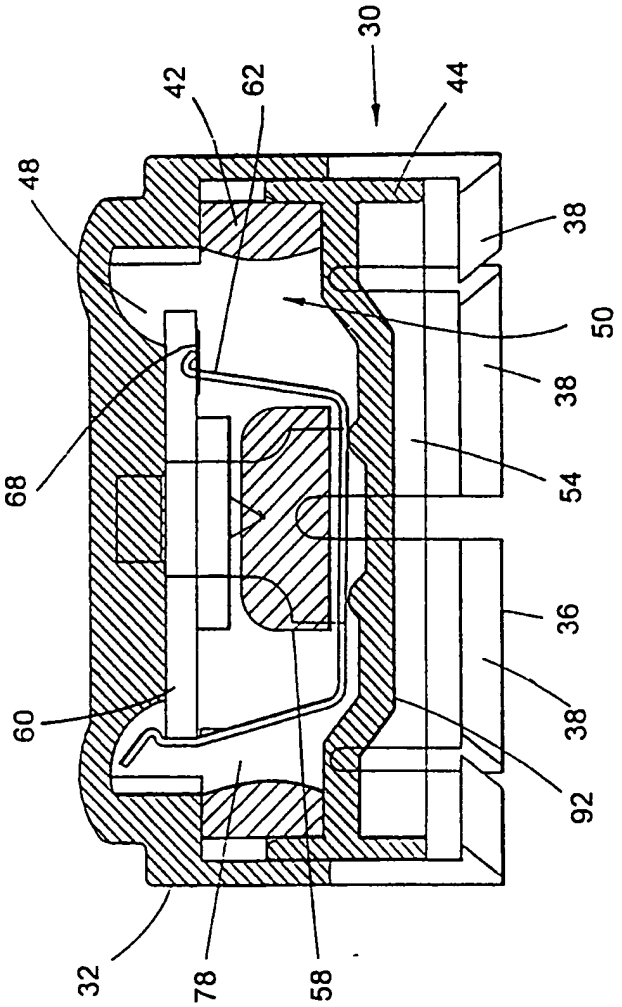
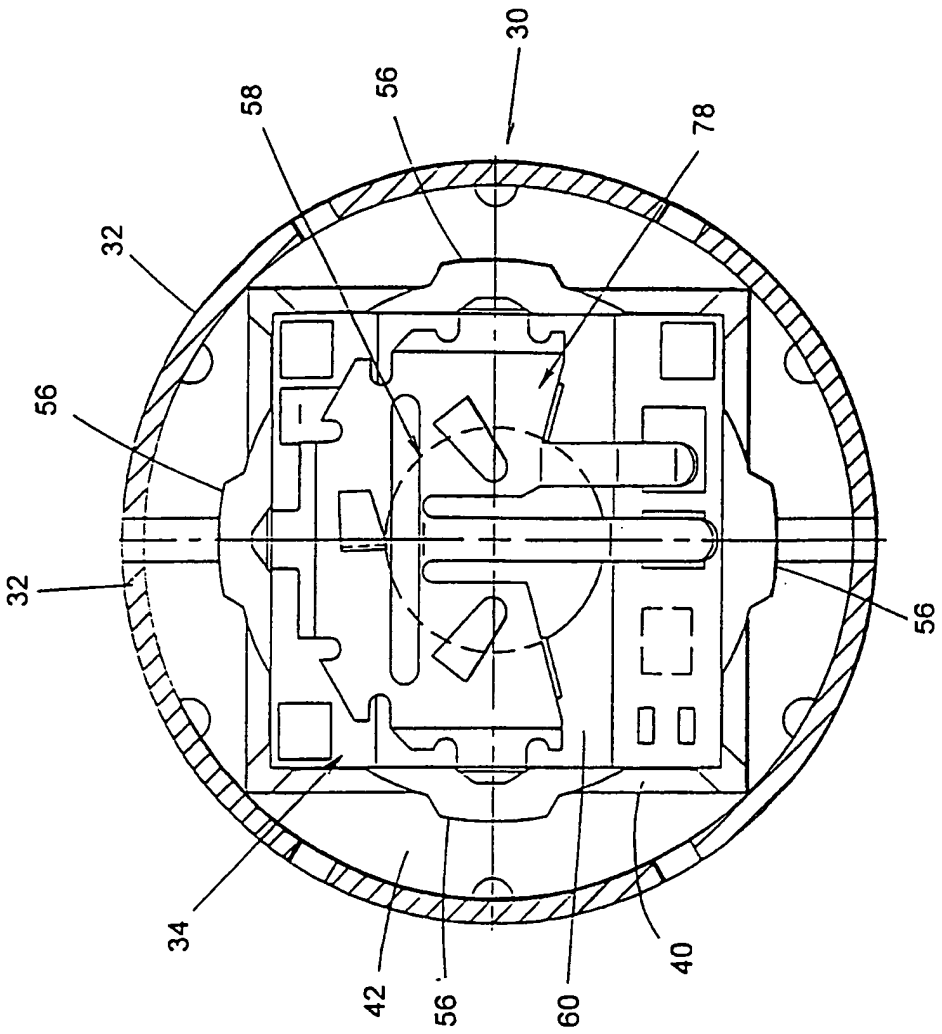


FIG. 8

FIG. 9



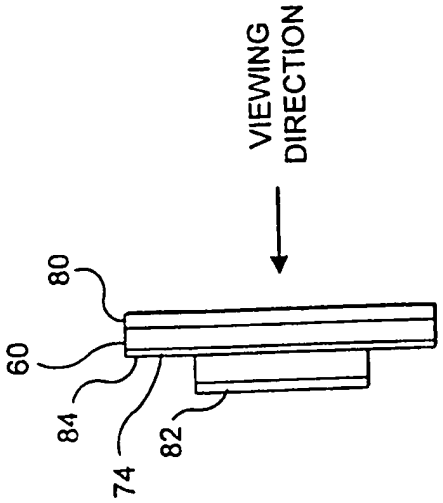


FIG. 12

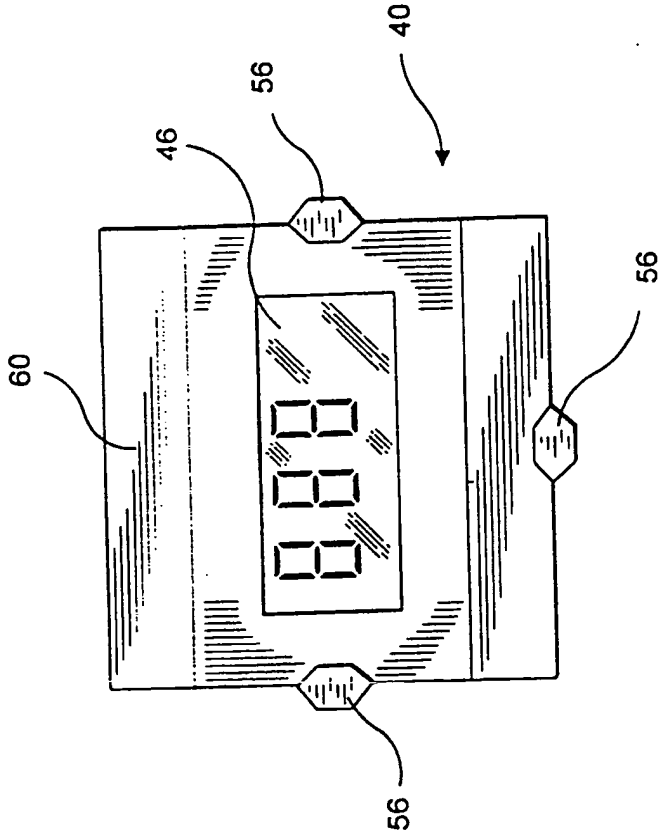
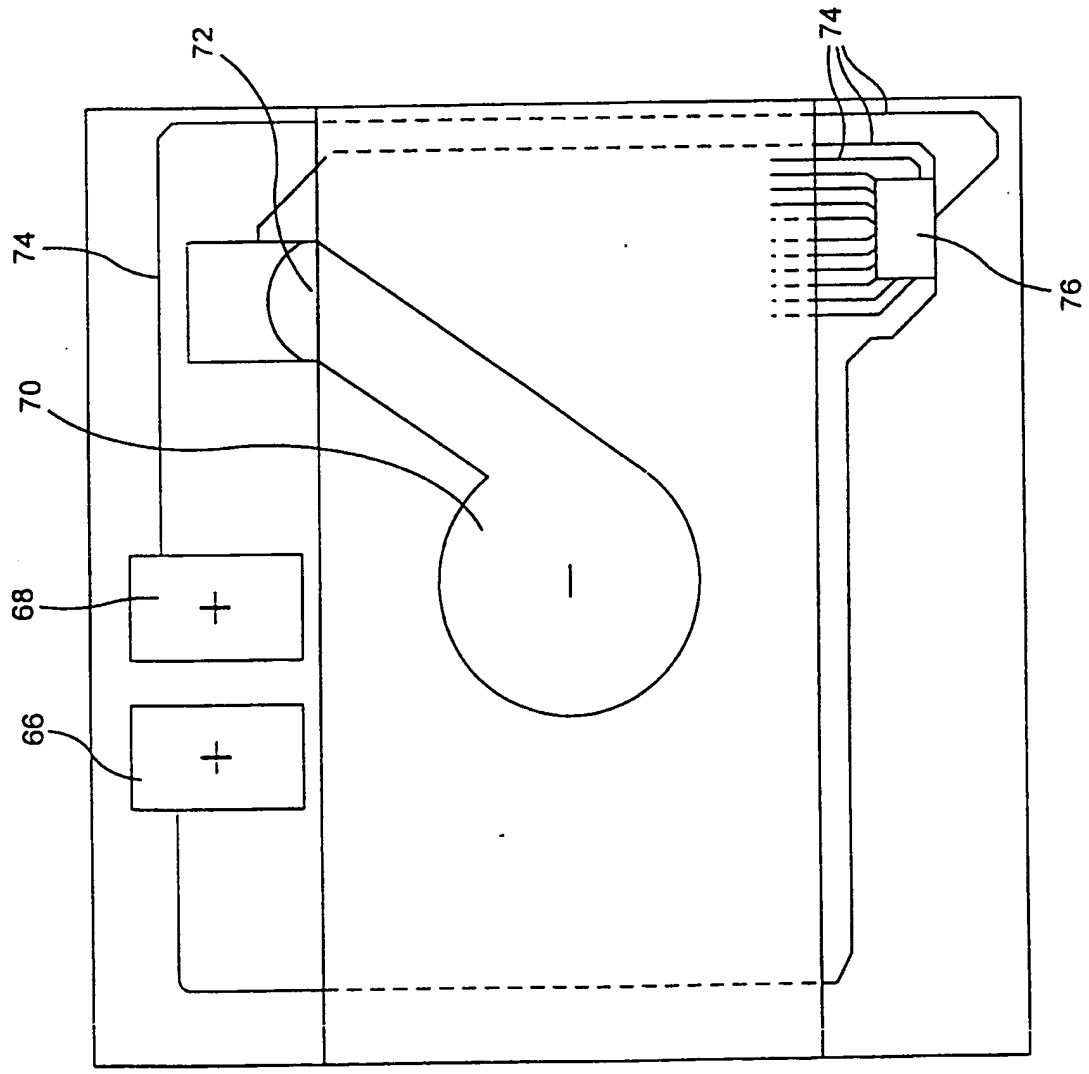


FIG. 10

FIG. 11



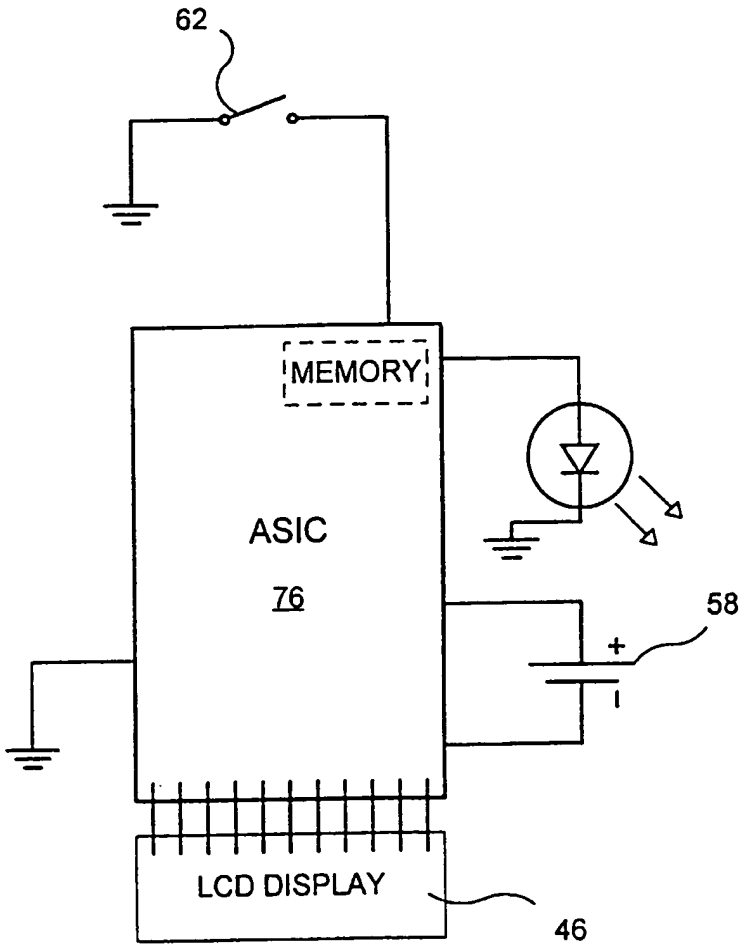


FIG. 13

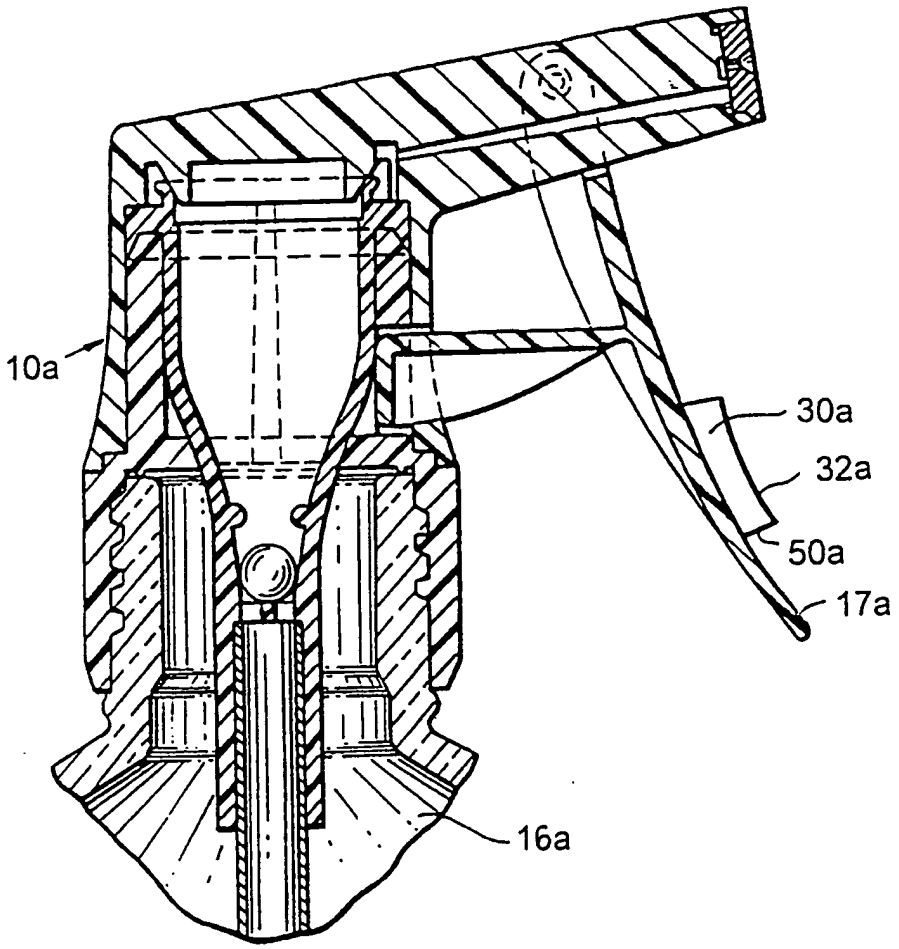


FIG. 14